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SENATE BILL 2285 By
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HOUSE BILL 3204
By Odom

AN ACT to amend Tennessee Code Annotated, Title 56 and Title 63, Chapter 10, relative to protecting medically vulnerable persons from economically motivated impediments to receiving the pharmaceutical care prescribed by their physicians.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 56, Chapter 8, is amended by adding the following as a new Part 4:

Section 56-8-401.

(a) This act may be known and cited as the "Patients' Right to Pharmaceutical Quality Act of 2002".

(b) The general assembly finds and declares that:

(1) Care management techniques impose burdens on sick persons and their families that are time-consuming, confusing, and financially costly.

(2) Economically-motivated coverage exclusions, tiered copays and other incentive-based cost-sharing requirements cause patients to have a financial interest in influencing the therapeutic decisions of their doctors.

(3) Economically-motivated switching of therapies:

(A) exposes a patient whose care is already well-managed to the possibility of new side effects and adverse interactions with co-existing therapies or diseases;

(B) creates confusion and administrative burdens for patients and families who must accommodate different dosing schedules, routes of administration, interactions with food and other medicines;

(C) is an inappropriate interference with the provider-patient relationship.

(4) Incentive-based cost-sharing requirements that are designed to punish or reward the selection of therapeutic interventions based solely on their cost or other attributes that do not take into account the patient's medical needs:

(A) unfairly shift the cost of health benefits to persons with non-preferred diseases, to the benefit of patients with preferred diseases. For example:

(i) punishing the choice of a brand name drug when there is no generic equivalent causes the person whose disease is treated only with a branded drug to subsidize the care of the person whose disease can be treated with a different drug that has both brand and generic versions.

(ii) punishing the choice of an injectable drug rather than a pill causes the person whose disease is treated only with an injectable to subsidize the care of the person whose disease can be treated with a different drug that is available in pill form; and

(B) are, therefore, ipso facto designed to discriminate against persons whose diseases are treated primarily with the disfavored

therapeutic interventions, in that they require the patient and the patient's family to choose between quality of care and cost.

(5) Economically-motivated prior authorization and coverage limitations, when used improperly:

(A) impose medically inappropriate delays in the receipt of medically necessary care in order for the health plan to complete its administrative processes, and by confusing or burdening patients and their families about whether or not the care prescribed by a physician is needed; and

(B) result in the de facto denial of medically necessary care prescribed by the patient's physician.

Section 56-8-402.

(a) It is unlawful for a health plan to request or require, directly or indirectly, as a condition of coverage for a refill or renewal of a prescription for a covered beneficiary, that a physician switch from a medication previously used for a particular indication to another medication based on economic considerations.

(b) It is unlawful for a health plan to request or require, directly or indirectly, as a condition of a covered beneficiary receiving favorable cost-sharing or administratively prompt refill or renewal of a prescription, that a physician switch from a medication previously used by the patient for a particular indication to another medication based on economic considerations.

Section 56-8-403.

(a) It is unlawful for a health plan, or its contracted benefit manager, to employ a care management technique for covered beneficiaries (including but not limited to implementation of a formulary, treatment protocol or guideline, step

therapy or other use of prior authorization) without assuring that its clinical foundation is consistent with quality patient care.

(b) The assurances required for purposes of this section include evidence of:

(1) clinically-based definitions for each "therapeutic class" of drugs;

(2) reliance on scientific and clinical data in updating formularies, protocols or treatment guidelines; and

(3) for any drug subject to prior authorization, a specific set of clinical criteria, available to physicians and patients, specifying when that drug is authorized for coverage.

Section 56-8-404. It is unlawful for a health plan to request or require physicians, pharmacies or covered beneficiaries to participate in programs that use clinical case management tools implemented using prior authorization or approval requirements unless:

(1) the prior authorization system provides for real-time receipt of requests, by voice mail, fax, or electronic transmission, on a twenty-four (24) hour basis, seven (7) days a week;

(2) the prior authorization system provides in-person answers to emergency requests by physician offices or pharmacies with telephone answering queues that do not exceed ten (10) minutes;

(3) any request for authorization or approval of a drug that the prescriber indicates is for an acute condition, including infection or exposure requiring treatment with antibiotics, acute pain, or life threatening symptoms, is answered in no more than four (4) hours from that authorization is requested by the clinician or pharmacy;

(4) any request for authorization or approval of a drug that the prescriber indicates is for a chronic or non-acute condition is answered in no more than twenty-four (24) hours of the time that authorization is requested by the clinician or pharmacy;

(5) in an emergency or, with respect to an acute condition, a failure (after an initial denial) to authorize a prescribed course of therapy within the same business day in which the requests commenced, the patient receives coverage of an initial course of therapy for an acute condition, or seven (7) days supply for a chronic condition; and

(6) no prior authorization requirement shall apply to renewals or refills of a prescription authorized by the same prescriber.

Section 56-8-405.

(a) The use by a health plan of a tiered copay or incentive-based cost-sharing requirement for covered beneficiaries that is based solely on the relative cost, therapeutic form, technology, regulatory status, or patent status of the therapeutic intervention is per se illegal discrimination against covered beneficiaries whose disease is treated with such interventions.

(b) All tiered copay and incentive-based cost-sharing requirements imposed on covered beneficiaries shall be limited to choices in which patients can take cost into account in making therapy selection decisions without sacrificing quality of care, for example, choice of dosing form for a given pharmaceutical entity, choice of generic substitution, and product convenience.

Section 56-8-406.

(a) Each covered beneficiary (or provider or other person on behalf of a patient) shall be provided with an opportunity for prompt review of a coverage denial for a drug prescribed for a medically accepted indication.

(b) A health plan shall complete its review of a request for review of a coverage denial within four (4) weeks of the date it is submitted by a patient, or provider or other person on behalf of a patient, whether orally or in writing.

(c) A patient, or provider or other person on behalf of a patient, may appeal from a health plan's adverse decision where:

(1) the health plan fails to issue a written confirmation of its decision regarding review of a coverage denial within seven (7) days; or

(2) the item is not excluded from the benefit package available to beneficiaries under the patient's plan, and the prescriber maintains that the coverage restriction imposed for the specific individual is a denial of medically necessary care.

(c) The health plan shall pay for a drug lawfully prescribed by a physician for a medically accepted indication throughout the pendency of an appeal of the denial of coverage for such drug under this section.

Section 56-8-407.

(a) A covered beneficiary (or a provider or other person on behalf of a beneficiary) who is successful in appealing a denial under §56-8-406 may:

(1) obtain payment retroactively for care rendered as of the date of the original prescription, including interest if the health plan failed to pay for the drug during the pendency of the appeal;

(2) obtain attorneys fees and court costs, including expert witness fees; and

(3) in cases where the court finds that the health plan acted with disregard for the physician's views regarding the course of therapy for the patient, obtain such compensation as the court deems appropriate up to one hundred thousand dollars ($100,000).

(b) A covered beneficiary (or a provider or other person on behalf of a beneficiary) who discovers that such beneficiary's physician's prescription has, during the previous five (5) years, been switched inconsistent with §56-8-402, or where payment for a drug has been denied based on criteria that are inconsistent with §56-8-403, may:

(1) in cases where the court finds that the health plan acted with disregard for the physician's views regarding the course of therapy for the patient, obtain such compensation as the court deems appropriate up to one hundred thousand dollars ($100,000); and

(2) obtain attorneys fees and court costs, including expert witness fees.

(c) A covered beneficiary (or a provider or other person on behalf of a beneficiary) who discovers that such beneficiary has paid cost-sharing requirements during the previous five (5) years that are inconsistent with §56-8-405, may:

(1) recover all payments in excess of what would have been made had the health plan been in compliance with §56-8-405, plus interest;

(2) obtain such compensation for the discriminatory treatment as the court deems appropriate to deter the health plan or others from engaging in such a course of conduct; and

(3) may obtain attorneys fees and court costs, including expert witness fees.

(d) A health plan's failure to comply with §§56-8-402, 56-8-403, 56-8-404, 56-8-405 or 56-8-406 is an unfair business practice in this state.

(1) A person aggrieved by such an unfair business practice:

(A) may obtain injunctive relief in the courts of this state; and

(B) upon the grant of a preliminary or permanent injunction under this subsection shall be eligible for attorneys fees and court costs paid by the health plan.

(2) A health plan that is the subject of injunctive relief under this section:

(A) shall be ineligible to provide services to covered beneficiaries for at least one (1) year following the date it has established to the satisfaction of the court that all the programs through which it provides care to covered beneficiaries comply with §§ 56-8-402, 56-8-403, 56-8-404, 56-8-405 or 56-8-406; and

(B) in the discretion of the court, shall not be licensed to offer benefits in this state until such time as all of its products offered in this state comply with §§ 56-8-402, 56-8-403, 56-8-404, 56-8-405 or 56-8-406.

(e) Operating a health plan that does not make arrangements to operate in compliance with §§ 56-8-402, 56-8-403 or 56-8-404 is impermissible interference with the provider-patient relationship. A physician, pharmacist or other health care professional licensed in this state may obtain relief from a violation of this subsection in the courts of this state, including:

(1) preliminary or permanent injunction from rules for provider participation in a health plan that fails to comply with §§56-8-402, 56-8-403 or 56-8-404;

(2) attorneys fees and court costs, including expert witness fees; and

(3) in cases where the court finds that the health plan acted with intentional disregard for a licensed physician's views regarding the course of therapy for a patient, obtain such compensation as the court deems appropriate to create a deterrent to such a course of conduct by the health plan or others in this state.

Section 56-8-408. For the purposes of this part:

(1) "Acute condition" means a symptom, condition, or disease that is expected to have a duration of two (2) weeks or less, or where prompt receipt of medication is needed for infection or exposure requiring antibiotics, for pain, or for life threatening symptoms.

(2) "Covered Beneficiary" means an individual who is eligible to receive care paid for in whole, or in part, by the state Medicaid program, Children's Health Program, or a State Pharmacy Assistance Program.

(3) "Chronic condition" means a symptom, condition, or disease that is expected to have a duration of more than two (2) weeks.

(4) "Emergency" means a situation in which a physician indicates that delay of care exclusively to fulfill administrative requirements would be medically inappropriate, and shall include any administrative delay that results from a failure to respond to a request for authorization within the time periods required by this part.

(5) "Health Plan" means:

(A) the health benefits program available in this state to individuals who are eligible for Medicaid, the State Children's Health Plan, or a State Pharmacy Assistance Program; and

(B) a health maintenance organization, insurance organization, or other service plan licensed to operate in this state that offers or administers benefits under any of the programs in paragraph (A).

(6) "Medically accepted indication" means use of a drug for an indication that is specified in the drug's labeling, the drug compendia, or peer-reviewed medical literature.

SECTION 2. If any provision of this act or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of the act which can be given effect without the invalid provision or application, and to that end the provisions of this act are declared to be severable.

SECTION 3. The commissioner of commerce and insurance is authorized to promulgate rules and regulations to effectuate the purposes of this act. All such rules and regulations shall be promulgated in accordance with the provisions of Tennessee Code Annotated, Title 4, Chapter 5.

SECTION 4. This act shall take effect July 1, 2002, the public welfare requiring it.